K121931

p. 1 of 2

5. 510K Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807 and in particular 21 CFR §807.92, the following summary of information is provided:

OCT 19 2012

Applicant Information

Christine Vergely
Regulatory Affairs Manager
Neurovision Medical Products, Inc.
2225 Sperry Ave., Suite 1000
Ventura, CA 93003
PH 805-866-6999
Fax: 413-410-4579
christie@neurovisionmedical.com

Date of Summary: 10/10/12

Device Identification:

Trade Name: Neurovision Stimulating Dissector
Common Name: Neurovision Dissection/Stimulating Accessory
Classification Name: Surgical nerve stimulator/locator, 21 CFR 874.1820 Class II, Product Code: ETN

Predicate Devices

Stimulating Hemostat (K895676); Nerve Locator Monitor (K110140)

Device Description

The Stimulating Hemostat and other manual instruments are dissectors modified by insulation and application of a connecting pin for connection to nerve stimulation. The specific instruments cleared for this modification in this 510(k) are the following:

- Scissors Hinge Hemostat, curved, fine
- Box Hinge Hemostat, curved, fine
- Scissors Hinge Hemostat, right angle
- Mosquito Hemostat, curved, fine
- Halsted Hemostat, curved
- Crile Hemostat, curved
- Kelly Hemostat, curved
- Schnidt Hemostat, curved, fine
- Gemini Hemostat, curved, fine
- Petit Point Mixter, right angle
- McCabe Dissector, curved, fine
- Jacobson Mosquito, curved, fine
- House Rosen Elevator, coarse
- Sheehy "Weapon", Large (2.4 mm)
- Probe, Ball tip
- Suction Stimulator (Neurovision model)

Intended Use

This device is a manual surgical instrument for performance of dissection and nerve stimulation input to living tissue concurrently.

Technological Characteristics of Device in Relation to Predicate Devices

The Stimulating Hemostat approved under K895676 was insulated only on its fingerings and arms but not over the box hinge or tip. Subsequent work has shown that hinged (both box and scissor type) devices can be insulated down to the tips, providing more precise localization of nerve and reduced problems with shorting of the instrument to the wound edges. For over 23 years, the additional instruments in this submission have been modified using the same materials to insulate, and the same method for insulating as the predicate. These modified instruments present no additional issues with sterilization, safety or effectiveness.

Performance Testing

The reprocessing validation testing used to create and validate the cleaning and sterilization instructions were conducted according to the standard ANSI/AAMI ST 79: 2006 and guidance documents AAMI TIR 12:2004 and AAMI TIR 30:2011.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 19 2012

Neurovision Medical Products, Inc.
c/o Ms. Christine Vergely
Regulatory Manager
2225 Sperry Avenue, Suite 1000
Ventura, CA 93003

Re: K121931
Trade/Device Name: Neurovision Dissection/Stimulating Accessory
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN
Dated: September 18, 2012
Received: September 19, 2012

Dear Ms. Vergely:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

4. Indications for Use:

Device Name: Neurovision Dissection/Stimulating Accessory

This device is a manual surgical instrument for performance of dissection and nerve stimulation input to living tissue concurrently.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

X

Prescription Use
(Per 21 CFR 801.109)

510(k) Number K121931